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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/629,291	07/28/2003	Guangqiang Jiang	A329-USA	6474
24677	7590	12/07/2007		
ALFRED E. MANN FOUNDATION FOR SCIENTIFIC RESEARCH PO BOX 905 SANTA CLARITA, CA 91380			EXAMINER GEDEON, BRIAN T	
			ART UNIT 3766	PAPER NUMBER
			MAIL DATE 12/07/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

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<b>Office Action Summary</b>	Application No.	Applicant(s)	
	10/629,291	JIANG ET AL.	
	Examiner	Art Unit	
	Brian T. Gedeon	3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 25 September 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-3 and 5-28 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3 and 5-28 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Response to Amendment***

This action is in response to the amendment after non-final filed 25 September 2007.

### ***Claim Objections***

Claim 5 is objected to because of the following informalities: claim 5 depends on a withdrawn claim. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-3 and 5-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tsukuma et al. (US Patent no. 4,587,225) in view of Whitehurst et al. (US Patent no. 6,735,475).

In regard to claims 1, 10, 13, 19, and 23, Tsukuma et al. disclose a method for producing a long-lived, stabilized tetragonal zirconia polycrystal ceramic, col 1 lines 6-16 and col 2 lines 3-14, comprising the step of hot isostatic pressing said ceramic at a controlled temperature, at a controlled pressure, col 2 lines 14-27 and col 8 line 50 – col 9 line 21, and in a controlled atmosphere to achieve an average grain size of less than about 0.5 micron, col 3 lines 60-62, to substantially eliminate open porosity and to

increase bulk density to about 100%, col 2 lines 10-12 of theoretical, thereby substantially eliminating low-temperature degradation of said polycrystal ceramic.

However, Tsukuma et al. does not teach the use of the ceramic material to be used as a housing for an implantable medical device. Whitehurst et al. disclose a microstimulator, known as the BION, col 8 lines 31-34, with a housing that can be fabricated from ceramic, col 16 lines 1-3, with dimensions of 3-5 mm or less in diameter, 20-35 mm or less in length, col 15 lines 50-53, wherein the microstimulator housing is a thin elongated cylinder, col 15 lines 56-59. The microstimulator may be inserted into a patient via a hypodermic syringe, col 15 lines 60-62. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the ceramic formed by Tsukuma et al. as a microstimulator housing since Whitehurst et al. teach that microstimulator housings can be made from ceramic.

In regard to claims 2, 3, 11, and 12, the tetragonal zirconia polycrystal is stabilized with between 1.5 to 5 mol percent Yttria, col 8 lines 50-53.

In regard to claims 5 and 14, Whitehurst et al. describe a implantable microstimulator housing with dimensions of 3-5 mm or less in diameter, 20-35 mm or less in length, col 15 lines 50-53, wherein the microstimulator housing is a thin elongated cylinder, col 15 lines 56-59. It would have been obvious to one with ordinary skill in the art at the time the invention was made to utilize 100 mm or less for length, 10 mm or less for diameter, and 2 mm or less for wall thickness of the claimed tube since our reviewing courts have held that where the only difference between the prior art and the claims was a recitation of relative dimensions of the claimed device and a device

having the claimed relative dimensions would not perform differently than the prior art device, the claimed device was not patentably distinct from the prior art device. *Gardner v. TEC Systems, Inc.*, 725 F.2d 1338, 220 USPQ 777 (Fed. Cir. 1984), cert. denied, 469 U.S. 830, 225 USPQ 232 (1984). It is also well known in the art that the dimensions of the BION microstimulator, which is the embodiment of the Whitehurst et al., are of the millimeter scale or smaller.

In regard to claims 6, 15, 21, and 25, the hot isostatic pressing of Tsukuma et al. is controlled at a temperature between 1300<sup>0</sup> C to 1600<sup>0</sup> C, col 8 lines 61-65.

In regard to claims 7, 16, 20, and 26, the hot isostatic pressing of Tsukuma et al. is controlled at a pressure between 50 to 200 MPa, col 8 lines 61-66.

In regard to claims 8, 9, 17, 18, 22, and 27, the hot isostatic pressing of Tsukuma et al. is controlled at an atmosphere in argon, col 8 lines 61-66.

In regard to claim 24, the ceramic of Tsukuma et al. has a three point bending stress of at least 1700 MPa, col 3 lines 21-35.

In regard to claim 28, the hot isostatic pressing of Tsukuma et al. is controlled at an atmosphere in argon for 30 minutes, col 8 lines 61-66.

### ***Response to Arguments***

Applicant's arguments regarding claims 19-28 have been fully considered but they are not persuasive. Applicant argues that the Whitehurst et al. (US Patent no. 6,735,475) reference is disqualified as prior art since its publication date (i.e., the date of issue) is after the filing date of the instant application. The Whitehurst et al. reference

qualifies as a 35 U.S.C. 102(e) prior art in that it can be applied against claims as of its effective U.S. filing date, and not the date of its publication. MPEP 706.02(f) [R-3]. The effective filing date of the Whitehurst et al. reference is 24 January 2002, which is before the effective filing date of the instant application. Further, Whitehurst et al. qualifies as prior art under 35 U.S.C. 103(a) since a timely filed affidavit or disclosure establishing common ownership or joint research agreement was filed at the time the invention was made. MPEP 706.02(k) [R-5].

Applicant's arguments, see Remarks, filed 25 September 2007, with respect to the rejection(s) of claim(s) 1-3 and 6-9 under Tsukuma et al. (US Patent no. 4,587,225) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Tsukuma et al. (US Patent no. 4,587,225) in view of Whitehurst et al. (US Patent no. 6,735,475).

Applicant's arguments, see Remarks, filed 25 September 2007, with respect to the rejection(s) of claim(s) 4, 5, and 10-18 under Tsukuma et al. (US Patent no. 4,587,225) in view of Jiang have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Tsukuma et al. (US Patent no. 4,587,225) in view of Whitehurst et al. (US Patent no. 6,735,475).

***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP.

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian T. Gedeon whose telephone number is (571) 272-3447. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carl H. Layno can be reached on (571) 272-4949. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Application/Control Number:  
10/629,291  
Art Unit: 3766

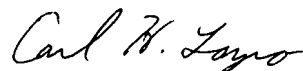
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Brian T. Gedeon  
Patent Examiner  
Art Unit 3766

BTG

Carl H. Layno  
Supervisory Patent Examiner  
Art Unit 3766



CARL LAYNO  
PRIMARY EXAMINER